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Docket No.: PF-0459 US

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Lal et al.

Title: HUMAN SIGNAL PEPTIDE-CONTAINING PROTEINS

Serial No.: 09/002,485

Filing Date: December 31, 1997

Examiner: Saoud, C.

Group Art Unit: 1647

BOX AF

Commissioner for Patents

Washington, D.C. 20231

**REPLY BRIEF ON APPEAL**

Sir:

This is Appellants' Reply Brief on Appeal under 37 C.F.R. 1.193(b)(1) (submitted in triplicate) in response to the Examiner's Answer dated November 26, 2001 in the above-identified application (the Lal '485 application).

**I. Introduction**

The Examiner does not deny the following:

1. that the claimed polynucleotide encodes a cytokine (Examiner's Answer at pp. 8-9); and
2. that all, or almost all, cytokines are useful.

It follows that the claimed invention is, by more than a reasonable probability, useful. There is no dispute that the applicant need show no more than a reasonable probability that the claimed invention is useful to meet the requirements of 35 U.S.C. §§101 and 112.

The Examiner never assails or even addresses this compelling logic. The Examiner continues to insist that the applicant prove not only reasonable probability of utility, but also the biological or physical function of the claimed invention.

Nothing in the law requires the applicant to prove biological function, and the Examiner does not point to anything in the law suggesting such a requirement. Indeed, the only law on point is to the contrary: it is settled law -- and the Examiner does not rebut this -- that how an invention works (that is, its function) is utterly irrelevant to the utility analysis. In short, the entirety of the Examiner's argument is based on the confusion between, and improper equation of, use and function.

The Examiner apparently would rely on *In re Kirk* for the proposition that the applicant must demonstrate biological function. *Kirk* requires no such thing. Indeed, *Kirk* is completely consistent with the requirement that the applicant need only show utility of the claimed invention to reasonable probability. In *Kirk*, the applicant could not show reasonable probability because the only fact alleged by the applicant was that the claimed invention is a steroid. Because so many steroids -- indeed most of them -- have absolutely no use whatsoever (in particular because they are synthetic and not naturally occurring), it followed that the applicant had not shown a reasonable probability of utility.

Application of the same logic to this case -- which the Examiner refuses to do -- yields a completely different result. In this case, the applicant has identified the claimed invention by association in a much better defined and narrower group: cytokines. As demonstrated above, because cytokines are predominantly useful, the applicant can state with great confidence that the claimed invention is useful. How the invention actually works is utterly irrelevant to the analysis.

**II. Responses to specific arguments by the Examiner**

1. The Examiner repeatedly asserts that the instant application does not disclose the biological role of the SEQ ID NO:25/102 (e.g, Examiner's Answer at p. 4, bottom; p. 5, top; p. 6, top; p. 7, middle, etc.). While Appellants expressly do not concede that this assertion is correct, Appellants also assert that there is nothing in the law that requires a patent applicant to establish biological activity. It is settled Patent Law that knowing how an invention works is not necessary to obtain a patent.

If one skilled in the art recognized that, for example, a microarray comprising a polynucleotide of SEQ ID NO:102 is useful for monitoring the effect of a drug on chemokine expression levels, the criterion for utility is satisfied regardless of whether the precise biological function of SEQ ID NO:25/102 is known. If the practitioner wished to further study the biological role of SEQ ID NO:25/102, e.g., in the absence and presence of the drug, this could be accomplished through the use of the polynucleotide and polypeptide data disclosed in the instant application. However, the use of SEQ ID NO:25/102 in monitoring the effect of, e.g., drug treatment, is already a "real-world" utility without further study. Accordingly, the claimed invention is not merely an object of further study (see Examiner's Answer, e.g., at p. 14, bottom).

2. The Examiner contends (Examiner's Answer at pp. 9-10) that individual members of the cytokine family have different functions, and therefore do not share the same use. The Examiner confuses, once again, function with use. These are not synonymous. Despite having different biological functions, the cytokines can indeed have many common uses, such as toxicology controls. In any event, it does not matter that there may be more than one use for cytokines. The point for the purposes of the utility standard is that all cytokines are indeed useful, which proves more than probable utility of the claimed invention.

3. The Examiner argues on pages 9-10 of the Examiner's Answer (see also pp. 12-14) that the Specification does not disclose whether the claimed polynucleotides are differentially expressed in different cells or tissues. This is irrelevant. Applicant need not demonstrate whether the invention is

differentially expressed, only whether it is useful. It is useful whether or not it is differentially expressed in any cells or tissues.

4. The Examiner argues (pages 18-19 of the Examiner's Answer) that use of the claimed polynucleotides in toxicology testing, drug discovery, and disease diagnosis is not sufficient to establish utility because these are general to the class of cellular proteins. The Examiner does not point to any law, however, that says a utility that is shared by a large class is somehow not a utility. If all of the class of proteins can be so used, then they all have utility. The issue is, once again, whether the claimed invention has any utility, not whether other compounds have a similar utility. Nothing in the law says that an invention must have a "unique" utility. Indeed, the whole notion of "well-established" utilities presupposes that many different inventions can have the exact same utility. If the Examiner's argument were correct, there could never be a well-established utility, because you could always find a generic group with the same utility!

**CONCLUSION**

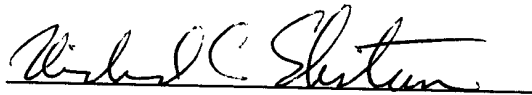
For the reasons set forth above and the reasons stated in the Appellants' Brief on Appeal, it is submitted that the Examiner's rejections of the claims on appeal should be reversed.

If the USPTO determines that any additional fees are due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

**This form is enclosed in triplicate.**

Respectfully submitted,  
INCYTE GENOMICS, INC.

Date: 28 January 2002



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